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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,344	08/10/2004	Alvin Needleman		3833

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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07/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,344

Applicant(s)

NEEDLEMAN ET AL.

Examiner

Snigdha Maewall

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Summary

1. Applicant is reminded that the office has not received IDS as of this date.

Claims 1-3 are pending in this application and claims 1-3 will be prosecuted on the merits. It is to be noted that the invention is drawn to the **composition claims 1-3**. The explanation as to how the composition functions as a nutritional intervention composition has been depicted under categories I through III.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 refers to (claim 4) in the first sentence. There is no antecedent basis for this claim. Claim 4 does not exist. Appropriate correction is required.

Claim 1 and subsection (c) under claim 1 comprise two sentences. A claim is rendered indefinite where broad and narrow limitations are recited. Appropriate correction is required. Claim 1 recites the limitation "such as" which makes the claim indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson (US PG Pub. No. 2004/0197377 A1) in view of the combination of following references:

Hudson et al. (US Patent 6,503,543 B1),

Pollack (US Patent No. 4,650,789),

Merianos et al. (US Patent No. 5,942,240) and

Zolotariov et al. (US PG PUB 2004/0265344 A1).

Thompson discloses an invention comprising 5-Hydroxytryptophan (5-HTP) an amino acid that is extracted from the seeds of the West African Griffonia plant. Intake of 5-HTP

has been shown to be effective in aiding in production of neurotransmitter "serotonin" which helps in restoring serotonin levels. Low serotonin levels cause sleep apnea, headaches, insomnia and anxiety etc. (see page 1, paragraph [0008] and page 2, paragraph [0027 and [0031])).

Thompson does not teach free tryptophan.

Hudson et al. teaches source and uses of tryptophan (title). Tryptophan helps in treating insomnia. After absorption tryptophan circulates in the blood (approximately 80% bound to plasma albumin with the remaining 20% circulating as free tryptophan, which metabolizes into serotonin. Tryptophan's metabolism to serotonin serves well in conditions where depleted serotonin levels exist such as depression and eating disorders etc. (see column 1, lines 5-28).

It would have been obvious to one of ordinary skilled in the art at the time the invention was made to incorporate tryptophan in the composition forwarded by Thompson because tryptophan metabolizes to serotonin, which helps in treating medical conditions.

Hudson et al. does not teach niacin, pyridoxine and carbohydrates.

Pollack teaches a composition comprising niacin, pyridoxine, salicylate and carbohydrate, which help in production of neurotransmitter serotonin (abstract).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate niacin, pyridoxine and carbohydrate in the composition forwarded by Thompson and Hudson et al. comprising 5-HTP and tryptophan because they help in increasing serotonin levels.

Pollack does not teach Aloe, freeze dried powder 200X, a source of salicylic acid.

Merianos et al. and Zolotariov et al. teach Aloe powder 200X in antimicrobial emulsion composition (see column 3 under Anionic Emulsion) and Zolotariov et al. teach the use of aloe in healing wounds and its anti-inflammatory effect due to various constituents of aloe such as salicylates, minerals, sterols and vitamins etc. (see page 1 and 2, paragraph [0012], [0016] and [0019]). With respect to various claimed amounts, it is the position of the examiner that optimization of various amounts would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate aloe in the composition forwarded by Hudson and Pollack because of aloe's antimicrobial and anti-inflammatory benefits.

A skilled artisan would have been motivated to prepare a composition comprising aloe freeze dried powder 200X, 5-HTP, tryptophan, niacin and pyridoxine with a reasonable expectation of success.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers et al. (US Patent No. 5,932,561) in view Dente (US Patent No. 6,277,396 B1).

Meyers et al. teaches a dietary supplement the binds lipid to aid in weight loss and reduce cholesterol comprising chitosan and aloin (aloe saponins) (abstract).

Meyers et al. do not teach a source of hydroxycitric acid from Garcinia cambogia.

Dente teaches a dietary supplement comprising adrenal support substance or thermogenic substance (abstract). The composition comprises blood sugar regulating components such as Garcinia cambogia, Bitter melon, fenugreek, chromium polynicotinate, zinc and magnesium etc. (column 2, lines 5-15). With respect to various claimed amounts, it is the position of the examiner that optimization of various amounts would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate garcinia cambogia in the formulation provided by Meyers et al. because it helps in blood sugar regulation. A skilled artisan would have been motivated to prepare a composition comprising chitosan, aloe saponin and garcinia cambogia with a reasonable expectation of success.

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dente (US Patent No. 6,277,396 B1) in view of Udell et al. (US Patent No. 6,784,206 B2) and further in view of Slaga et al. (US patent No. 6,451,341 B1).

The teachings of Dente have been discussed above. Although Dente teaches chromium polynicotinate, fenugreek seed and Bitter melon fruit, Dente does not teach Lagerstroemia speciosa (Leaf). Udell et al. discloses a soft gelatin capsule comprising Lagersroemia spciosa, which helps in moderate weight loss through blood sugar maintenance (abstract). It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate Lagerstroemia speciosa in the

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composition forwarded by Dente because it helps in weight loss by regulating blood sugar.

Udell et al. does not teach Vanadyl sulfate and Magnesium aspartate. Slaga et al. discloses cancer protective vitamins, minerals and other beneficial supplements in association with oil, enzymes and amino acids etc. in a dietary supplement formulation (abstract). Slaga et al. further disclose that magnesium is a mineral essential for every biological process including glucose metabolism etc. and vanadium is a trace mineral found in diet which functions in lipid metabolism, glucose and bone metabolism. The dosage of vanadium includes vanadyl sulfate. Potassium and magnesium aspartate play major role in transmission of nerve impulses and the release of insulin (see column 15, lines 50-65, column 16, lines 15-20, column 16 and 17, lines 66-67 and 1-10 respectively). With respect to various claimed amounts, it is the position of the examiner that optimization of various amounts would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations.

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate vanadyl sulfate and magnesium aspartate because they play vital role in biological processes. Based on the various advantages associated with various components as stated above, a skilled artisan would have been motivated to formulate a composition comprising fenugreek seed, bitter melon fruit, lagerstroemia speciosa, chromium polynicotinate, vanadium and magnesium with a reasonable expectation of success.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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Primary Examiner
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